



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/705,924	11/06/2000	Heinrich Planck	24446	8132

7590

07/23/2002

NATH & ASSOCIATES

Sixth Floor
1030 15th Street, N.W.
Washington, DC 20005

EXAMINER

PIERCE, JEREMY R

ART UNIT

PAPER NUMBER

1771

DATE MAILED: 07/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/705,924

Applicant(s)

PLANCK ET AL.

Examiner

Jeremy R. Pierce

Art Unit

1771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-73 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5,6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claims 30-73 are objected to because of the following informalities: The claims should be written in complete sentence form. Instead of "Flat implant", the sentence should be begin with "A flat implant". Additionally, the preamble of "Flat implant" should also be changed. The term flat implies an insignificant length in a third dimension, but a thickness of the two-layer implant is claimed in dependent claim 34. Thus, the implant would seem to be not flat at all. The Examiner would suggest other claim language, such as "planar implant" or "thin implant", depending on the manner in which the Applicant wanted to describe the implant. The claim language is confusing for claims 33, 37, 57, 64, and 65. Claim 33 introduces "a monofilament", but does not specifically associate a monofilament to the previously claimed "textile fabric structures" from claim 30. Claim 37 introduces "at least two net structures", but does not specifically associate the net structures with the previously claimed "textile fabric structures" from claim 30. Claims 57, 64, and 65 introduce "absorbable" and "non-absorbable" materials to the claims without associating them to the "textile fabric structures" from claim 30. The claims would be less confusing if they particularly pointed out the association of the new limitations, i.e. "a monofilament", "net structures", "absorbable material", and "non-absorbable material", with the "textile fabric structures" from claim 30. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 46 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 46 cites "the structure pores are openings and overlap roughly by half".
How do openings overlap one another by half?

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 30, 35-39, 41-48, 54, 65, and 67-72 are rejected under 35 U.S.C. 102(b) as being anticipated by Tormala et al. (WO 99/51163).

Tormala et al. disclose a hernia mesh that comprises a rapidly degradable first layer and more slowly degradable second layer (page 3, lines 4-5). The layers are formed from knitted fabrics into a porous mesh (page 6, lines 6-9). The two layers have different pore structures, where the first layer has pores between 50 and 1000 microns (page 5, line 14) and the second layer has pores between 0.1 to 2.0 millimeters (page 5, lines 18-19). With regard to claim 45, the pores of the two knitted fabrics would not be aligned with one another because of the difference in pore sizes between the two layers. With regard to claim 48, the pore sizes of the meshes would increase as the material is absorbed in the body.

6. Claims 30-39, 43, 44, 64, and 67-72 rejected under 35 U.S.C. 102(e) as being anticipated by Eldridge et al. (U.S. Patent No. 6,120,539).

Eldridge et al. disclose a prosthetic repair fabric comprising a first sheet of porous and tissue infiltratable material and a second sheet united with the first sheet (column 1, lines 44-52). The dual layer fabric may comprise two warp knit fabrics or two fabrics with different knit patterns (column 3, lines 20-28). In one embodiment, the two fabrics can comprise sheets of warp knitted polypropylene monofilament (column 1, line 65). With regard to claims 33 and 34, the reference cites fabric knitted from 0.006 inch polypropylene monofilament, which is roughly equal to 150 microns.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 55-63, 66, and 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tormala et al.

Tormala et al. do not disclose various claimed properties such as weight per unit area, strength, bursting pressure, bursting elongation, extensibility, and tearing strength. However, modification of material to obtain desired values in these properties is well known in the art of making prosthetic textile fabrics. If not already inherent by the material of Tormala et al., it would have been obvious to one having ordinary skill in the art to modify the prosthetic textile fabric disclosed by Tormala et al. with the claimed properties in order to create a fabric with desired suitability for its intended use, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). With regard to claims 66 and 73, Tormala et al. do not specifically cite using the fabric in the form of a belt for supporting the female urethra. However, it is well within the knowledge of a person of ordinary skill in the art to use prosthetic textiles in various parts of the body.

9. Claims 41, 42, 55-63, 66, and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eldridge et al.

With regard to claims 41 and 42, Eldridge et al. do not disclose the pore size of the knitted fabrics. It would have been obvious to one having ordinary skill in the art to manufacture the fabric with a pore size between 0.5 and 5 mm in order to create a fabric with sufficient pore space to allow tissue to grow into it, as is commonly known in the art. With regard to claims 55-63, Eldridge et al. do not disclose various claimed properties such as weight per unit area, strength, bursting pressure, bursting elongation, extensibility, and tearing strength. However, modification of material to obtain desired values in these properties is well known in the art of making prosthetic textile fabrics. If not already inherent by the material of Eldridge et al., it would have been obvious to one having ordinary skill in the art to modify the prosthetic textile fabric disclosed by Eldridge et al. with the claimed properties in order to create a fabric with desired suitability for its intended use, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). With regard to claims 66 and 73, Eldridge et al. do not specifically cite using the fabric in the form of a belt for supporting the female urethra. However, it is well within the knowledge of a person of ordinary skill in the art to use prosthetic textiles in various parts of the body.

10. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eldridge et al. or Tormala et al. in view of Titone et al. (U.S. Patent No. 5,569,273).

Neither Eldridge et al. nor Tormala et al. disclose knitting the mesh in a hexagonal shape. Titone et al. teach a hexagonal mesh fabric used in hernia repair that provides desired performance and physical characteristics (column 1, lines 47-61). It

would have been obvious to one having ordinary skill in the art to make the prosthetic fabrics of Eldridge et al. or Tormala et al. with a hexagonal shape as a matter of design choice in providing desired strength and performance characteristics, as taught by Titone et al.

11. Claims 49 and 51-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tormala et al. in view of Dumican (U.S. Patent No. 4,871,365).

Tormala et al. do teach manufacturing the layers of two different absorbable polymers that degrade at different rates, but do not teach one of the polymers be entirely non-absorbable. Dumican teaches a 50:50 mix of absorbable and non-absorbable material in a prosthetic implant (column 2, lines 17-33). It would have been obvious to one having ordinary skill in the art to modify the second layer of Tormala et al. from a slowly degrading polymer to a non-absorbable polymer, so that the material can be used as a prosthetic in instances where a permanent implant is required, as taught to be known by Dumican.

12. Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tormala et al. in view of Dumican as applied to claim 49 above, and further in view of Titone et al. as applied to claim 40 above.


Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: U.S. Patent No. 3,463,158 to Schmitt et al and U.S. Patent No. 5,888,609 to Karttunen.

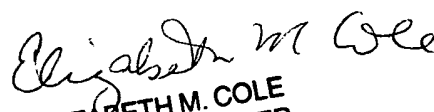
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeremy R. Pierce whose telephone number is (703) 605-4243. The examiner can normally be reached on Monday-Thursday 7-4:30 and alternate Fridays 7-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel Morris can be reached on (703) 308-2414. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.


Jeremy R. Pierce
Examiner
Art Unit 1771

July 15, 2002


ELIZABETH M. COLE
PRIMARY EXAMINER